REMARKS

Review and reconsideration of the non-final Office Action mailed May 24, 2011 (hereinafter "Office Action"), is respectfully requested in view of the arguments made herein. No fees are believed due; however, the Commissioner is hereby authorized to charge any deficiency or credit any surplus to Deposit Account No. 04-1679.

In the Office Action, claims 36-47 were pending, with claims 36-42 and 44-46 being drawn to an elected invention. Claims 36-42 and 44-46 stand rejected under one or more of 35 U.S.C. §112, second paragraph, and 35 U.S.C. §103(a). By this Amendment, claims 36, 38, 45 and 47 and are amended, and claim 48 is added. No new matter is added.

The amendments presented herein have been made solely to expedite prosecution of the instant application to allowance and should not be construed as an indication of Applicant's agreement with or acquiescence to the Examiner's position. Accordingly, Applicant expressly maintains the right to pursue broader subject matter through subsequent amendments, continuation or divisional applications, reexamination or reissue proceedings, and all other available means. The rejections and responses thereto are set forth fully below.

Claim Rejections – 35 USC § 112, Second Paragraph

Claims 36-42 and 44-46 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant claims as the invention. In particular, the rejection relates to the phrase "an antimicrobial and non-cytotoxic layered material." Applicant notes that objectionable phrase has been deleted from claim 36 and respectfully submits that the specification defines the terms at issue. *See, e.g.*, Specification, Page 3, ln. 19-26 and Page 17, ln. 23 – Page 18, ln. 9. Accordingly, Applicant respectfully requests that the rejections based on 35 U.S.C. § 112, second paragraph, be withdrawn.

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Claim Rejections – 35 USC §103(a)

In the Office Action, claims 36-42, 45 and 46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 7,820,284 by Terry ("Terry") in view of U.S. Patent No. 7,157,145 by Vissing et al. ("Vissing"). In the Office Action, claim 44 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Terry in view of Vissing et al. as applied to claims 36-42, 45 and 46, and further in view of U.S. Patent No. 6,333,093 by Burrell et al. ("Burrell"). As set forth in amended claim 36, the claimed layered material is drawn to:

> 36. (Currently amended) A ~~An antimicrobial and non-cytotoxic~~ layered material, comprising:
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> a) a biocide layer having a biocidal active agent, and
>
> b) a transport control layer covering the biocide layer, having a thickness and porosity adjusted to release an antimicrobial and non-cytotoxic quantity of the biocidal active agent out of the biocide layer and through the transport control layer, wherein the transport control layer is a plasma polymer layer and/or a sputter-applied layer and wherein the transport control layer has a silicon content of 20 to 60%, a carbon content of 10 to 30%, and an oxygen content of 30 to 50%.

Terry (US 7,820,284) discloses (see claim 1) a ***microbe-resistant medical device*** comprising a substrate, a polymeric base coat applied to at least a portion of the substrate, at least one type of antimicrobial particle dispersed throughout the base coat; and a solid polymeric overcoat positioned over at least a portion of the base coat. The antimicrobial particles can be metals and metal salts, oxides and complexes (Terry, column 3, lines 59-60). The medical devices disclosed in Terry are either disposable or implantable (Terry, claim 20).

Terry specifically enumerates numerous options for the overcoats, none of which include any silicon, much less the claimed 20-60% silicon. While silicon produces hydrophobic polymers, Terry notes that nearly any hydrophilic polymer that can be dissolved in solvents can be used for the overcoat (Terry, column 4, lines 55-56). According to Terry (column 6, lines 36-41), the reasons for making the overcoat from a hydrophilic polymer are as follows: When hydrophilic polymers are used for the overcoat, the overcoated antimicrobial medical devices

provide increased surface lubricity and decreased surface area (as compared to the base coat) of the medical device. Consequently, increased patient comfort, decreased tissue irritation, and increased antimicrobial effectiveness are achieved. Thus, the purposeful selection of a hydrophilic polymer provides useful benefits, which teaches away from the use of silicon.

Vissing (US 7,157,145) discloses (see claims 1 and 2) an article comprising a substrate and a plasma polymer coating comprising silicon, oxygen and carbon bonded to the surface of the substrate wherein the coating contains at least 22 and at most 27 atomic percent Si, at least 25 and at most 50 atomic percent O and at least 25 and at most 50 atomic percent C based on its total atomic number without hydrogen and/or fluorine. Vissing discloses (Column 4, lines 25-28) that the plasma polymer coating should be applied only to areas of substrate where "easy cleaning is important." In this regard, Vissing discloses (Column 4, lines 12-24) the following articles are potential candidates for the plasma polymer coating:

> rims; hub cap; aluminium [sic] section, in particular for windows or showers; windows; trims (interior and exterior), in particular for cars, aircraft or rail vehicles; windmill vanes, aircraft outer skin or regions thereof; metal facing, in particular for houses, facing and coverings for kitchens and kitchen equipment; displays especially for kitchens; glazing; car body part; motor cycle components; drinks containers; paint containers; ink containers; watercolour cartridges; bottles; kitchen equipment; frying pan; information signs; warning signs; re-usable vessels for foods, such as, for example, bottles or tubs.

Vissing, Column 4, lines 12-24.

Clearly, none of these relate to medical devices, such as the coatings described in Terry. Thus, Vissing discloses silicon containing coatings that are not used in medical devices, while Terry discloses coatings that do not include silicon that are used for medical devices. A person of ordinary skill in the art would understand that these omissions were intentional on the part of both Vissing and Terry.

Critically, Vissing discloses (column 3, lines 59-62) that the plasma polymer coating preferably has an angle of contact with water of >90°, preferably >95°, and more preferentially >100°. Accordingly, the plasma polymer coating is preferably hydrophobic, whereas the over

coat of Terry is preferably hydrophilic. In addition, Terry expressly noted that using a hydrophilic overcoat was critical in order to provide increased patient comfort, decreased tissue irritation, and increased antimicrobial effectiveness are achieved. ***A person of skill in the art would clearly understand that these benefits for a medical device greatly outweigh the self-cleaning benefits of Vissing and would not substitute the overcoat of Terry with the self-cleaning coating of Vissing as suggested by the Office Action.***

At least for this reason, in contrast to the speculation presented in item 13 of the Office Action a skilled person would not modify the device of Terry so as to replace the hydrophilic polymer overcoat with the plasma polymer layer of Vissing. In particular, Terry and Vissing provide directly contradictory teachings regarding hydrophilicity and hydrophobicity. Terry unambiguously prescribes to make the overcoat form a hydrophilic polymer while Vissing specifically directs the skilled person to hydrophobic layers. Thus, a person skilled in the art would understand that this is because the over coat of Terry and the self-cleaning coating of Vissing are for completely different purposes and would not substitute one for the other.

Terry lists benefits which arise from the selection of a hydrophilic polymer – in particular, increased patient comfort, decreased tissue irritation, and increased antimicrobial effectiveness are achieved. A person skilled in the art would not readily compromise all these benefits for an easier cleaning of the surface. Particularly for the disposable or implantable medical devices disclosed in Terry, where self-cleaning would not be seen as a benefit. Thus, due to the loss of all the benefits which are related to hydrophilic polymers of Terry, the replacement of the hydrophilic polymer by the plasma polymer of Vissing cannot be considered as an "improvement" as alleged in the Office Action (page 5, item 13, last sentence).

At least for these reasons, the subject matter of claims 36-42, 45 and 46 is not obvious over Terry in view of Vissing. As Burrell does not correct the deficiencies identified above, the subject matter of claim 44 is not obvious over Terry in view of Vissing and Burrell. Accordingly, Applicant respectfully requests that all rejections based on the cited art be withdrawn.

Conclusion

For at least the reasons set forth above, the independent claims are believed to be allowable. In addition, the dependent claims are believed to be allowable due to their dependence on an allowable base claim and for further features recited therein. The application is believed to be in condition for immediate allowance. If any issues remain outstanding, Applicant invites the Examiner to call the undersigned Greg Lefkowitz (direct line 561-962-2110) if it is believed that a telephone interview would expedite the prosecution of the application to an allowance.

Respectfully submitted,

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